

(2) REMARKS

Unobviousness

Claims 1-5 have been rejected under 35 USC §103 as being unpatentable over patent abstract of Japan 10/319358 and patent abstract of Japan 10/108899 for the reasons set forth on pages 2 and 3 of the Office Action of January 15, 2003.

The Examiner states that applicants allege criticality of the differences in concentration used by the prior art, but the allegation is not well taken since the determination of optimum proportions or amounts is considered to be within the skill of the art in the absence of evidence to the contrary. The Examiner further states that applicants have presented no evidence to establish the unexpected or unobvious nature of the claimed invention. This rejection is respectfully traversed for the reasons previously stated by applicants and those developed below.

The statements by the examiner in the subject office action, in effect ignore applicants' stated position that JP-A-1 0-319358 does not teach or suggest that the claimed polyamines, such as polyallylamine, possess an antibacterial activity. Importantly, the comments of the examiner also fail to address applicants' presentation of legal and factual arguments that the data in the Description establishes a full and proper rebuttal to the present rejection, which is based on *prima facie* obviousness – not on any specific reasons given in the references themselves or from any presentation of logic as to why someone skilled in the art would be motivated to make the modifications necessary to meet the terms of the claims.

It appears that the examiner has not well considered applicants' arguments presented in the previous response dated May 13, 2003, from page 3, second paragraph to page 6, last line. Applicants believe that it is clear that the factual arguments made against the JP-A-1 0-319358 reference, especially, noting that the allylamine is used at different concentrations for

a different purpose, is sufficient to overcome a rejection based on *prima facie* obviousness. There is no evidence or reasoning presented to the contrary by the examiner. Indeed, the examiner has not specifically commented on how the person skilled in the art might be motivated from the deficient teachings of the reference to modify those teachings for applicants' new purpose and new concentrations. There is no logical reason apparent from either the reference or the Office Action as to why, specifically, the person skilled in the art would put aside the teachings of the reference and adapt those teachings to achieve a purpose not taught other than by applicants' own description.

The JP-A 10-319358 reference is directed to a distributing solution (shipping solution) used for preserving contact lenses in distribution process until patients purchase the lens after manufacturing.

JP-A-10-319358 teaches using a polyallylamine having allylamine recurring units as a component for suppressing a change of the basic curve of a contact lens at the time of the distribution in a concentration of not less than 0.1 w/v % (*i.e.*, not less than 100 ppm), preferably not less than 0.1 w/v % (*i.e.*, not less than 100,000 ppm).

JP-A-10-319358 does not teach or suggest that the polyallylamine has an antimicrobial activity. It is not expected therefrom that the polyallylamine exhibits a high antimicrobial activity at concentrations as low as 0.3 to 50 ppm.

The data in the specification, Table 1 at page 19, shows that the claimed compound possesses unexpected properties, namely antimicrobial activity. Although it appears that the data in the specification is proper evidence, a Rule 132 Declaration has been prepared affirming the data in the specification. The Declaration is presented in view of the absence of any comment in the Office Action of applicants' previous argument that the data in the specification is evidence of unobviousness. Applicants previously pointed out legal authority for the evidence being proper rebuttal, but there is no comment on it in the Office Action. Again, applicants point out that the test for obviousness is for the invention as a whole, and

applicants believe that the lack of suggestion in the references themselves for the change necessary to meet the terms of applicants' claims, the reference teachings contrary to applicants' invention and applicants' presentation of rebuttal evidence, taken together, form a firm basis for a conclusion of unobviousness, not obviousness.

Applicants further note that JP-A-10-319358 teaches away from applicants' proof of effectiveness for a new purpose upon which the present invention is based, where it teaches that the disclosed distributing solution may further contain an antiseptic agent. Simply, the JP-A-1 0-319358 disclosure notes that the polyallylamine is a component in the composition for suppressing a change of the base curve of contact lenses and suggests adding another additive to achieve the very effect which the examiner concludes is obvious. The antiseptic agents disclosed therein are known antiseptic agents such as phenylmercuric nitrate, benzalkonium chloride, hexamethylene biguanide and the like (see paragraphs [0034] and [0035] of the automatic machine translation). As stated above, JP-A-10-319358 does not teach or suggest that the polyallylamine has an antimicrobial activity. Clearly, a person having ordinary skill in the art reading the reference for what it fairly teaches would draw a conclusion opposite from that of the Office Action. If the person skilled in the art would know to modify the reference teachings as called for in the rejection, then there would be no need to add the further antimicrobial.

JP-A-10-108899 has been cited by the examiner to show that the use of secondary components such as a surface active agent as claimed in claims 2 and 4 in contact lens solutions is old and is well known (see page 3 of the first Office Action, dated January 15, 2003). However, this reference does not solve the deficiencies of the basic reference and provides no rational basis for combining it with the teachings of JP-A-1 0-319358 to achieve applicants' objectives.

JP-A-10-108899 is directed to a liquid preparation for contact lenses, which contains 0.1 to 10 ppm of polyhexamethylene biguanide (PHMB) as an antibacterial agent to which a non-ionic isotonic agent is incorporated so that PHMB can exhibit the antimicrobial activity at a low concentration.

Given the facts that JP-A-10-108899 does not disclose polyamines, and that JP-A-10-319358 teaches using polyamines for a different purpose than applicants and does not recognize the properties identified for applicants' use, there is no basis for continuing the rejection as made out, especially in light of the evidence of unobviousness to the contrary presented by applicants in their written description and now in the Declaration under 37 CFR §1.132.

Applicants have made a significant advance in the art and have described it in a manner that clearly distinguishes it patentably from the prior art. In addition, applicants have submitted evidence of unexpected results which is sufficient in nature and weight to overcome a rejection based on *prima facie* obviousness. Accordingly, reconsideration and withdrawal of the rejection and allowance of all pending claims are believed in order, and such actions are earnestly solicited.

Respectfully submitted,



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